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10/697,684	10/29/2003	Robert A. Kerr II		9813

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EXAMINER

MEHMOOD, JENNIFER

ART UNIT PAPER NUMBER

2612

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No. 10/697,684	Applicant(s) KERR ET AL.
Examiner Jennifer A. Mehmood	Art Unit 2612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-41 is/are allowed.
- 6) ☒ Claim(s) 1-17, 20-31 and 42 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date September 22, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Claim Objections

1. Many claims are objected to because of the following informalities: numerous spelling and typographic errors occur throughout many claims. For example: Claim 1, line 4 and Claim 42, lines 19 and 20 "at least one movable doors"; Claim 2, line 3 and claim 7, line 2 "at least one doors"; Claim 18, 3rd last line "verse"; Claim 42, line 24 "filing"; Claim 32, line 2 "at plurality of dosage". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12, 24, 25, 38, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 12, 24, 25, 38, and 41, the phrase "can be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 21-23, 26-29, 31, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Depeusinge (US 6,625,518).

For claim 1, Depeusinge discloses a remotely monitored medication delivery system comprising: at least one dosage containment unit defining an internal volume, each of the at least one containment units having at least one moveable door defining an opening thereto; a sensor in signal communication with each of the at least one moveable door for monitoring the status of said door and producing a signal indicative of said status; and a transmitter in signal communication with said sensor for receiving the signal from said sensor and transmitting the signal to a remote receiver (col 3, lns 65-67; col 4, lns 1-19; Fig. 1, items 10, 18, 11, 19).

For claims 20 and 21, Depeusinge discloses at least one internal memory device for at least temporarily storing signals and data generated by said system at least one of either prior to or after transmission by said transmitter (col 1, lns 56-58; col 4, lns 1-10; Fig. 1, items 1, 3, 11, 18).

For claim 22, Depeusinge discloses the system comprises a plurality of dosage containment units.

For claim 23, Depeusinge discloses said plurality of units are arranged in a sequential order such that each of the plurality of doors except a first door and a last door has one preceding door and one succeeding door, and wherein said system further comprises a mechanical interlock system engaged with said plurality of doors

such that the interlock system locks each succeeding door until the door immediately preceding said succeeding door is opened (col 3, Ins 28-36 and 47-51; Fig. 2, item 8).

For claim 26, Depeusinge discloses the system transmitter is designed to automatically transmit the signals indicative of the status of the at least one door at a predetermined time interval (col 3, Ins 37-40 and 65-67; col 4, Ins 1-9).

For claim 27, Depeusinge discloses a programmable timer, wherein the timer may be programmed with at least one medication dosage schedule having at least one medication event (col 2, Ins 48-52; col 3, Ins 37-40 and 65-67).

For claim 28, Depeusinge discloses an alarm in signal communication with said programmable timer such that when the at least one medication schedule indicates a medication event the alarm is activated to provide an indication to a patient (col 3, Ins 56-59; col 4 Ins 8-11 and 20-27; Fig. 1, item 17).

For claim 29, Depeusinge discloses a remote patient notification system in signal communication with said programmable timer such that when the at least one medication schedule indicates a medication event the remote patient notification system is activated to communicate the event to a patient remotely (col 3, Ins 56-58; col 4, Ins 20-31).

For claim 31, Depeusinge discloses at least one lock mounted on each of said at least one doors, wherein each said at least one lock is in signal communication with said programmable timer such that each said at least one lock is unlocked automatically when said programmable timer indicates the occurrence of a medication event (col 3, Ins 37-40, 47-51, and 65-67).

For claim 42, the claim is interpreted and rejected for the same reasons as stated in the rejection of claim 1 as stated above. In addition, Depeusinge discloses filling each of said at least one dosage containment units with at least one medication dosage; and monitoring said remote receiver to determine the patient's compliance with a medication schedule (col 3, Ins 9-19).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-4, 7-9, 14, 16, 17, 25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518), and further in view of De La Huerga (US 6,529,446).

For claim 2, Depeusinge discloses said transmitter is activated to send the signal automatically when one of said sensors senses that one of the at least one doors does not open (col 4, Ins 8-10). De La Huerga, however, discloses a sensor that senses if a door has been opened (col 7, Ins 9-25; col 9, Ins 59-67; col 10, Ins 1-3). It would have been obvious to one of ordinary skill in the art, at the time the invention was made to automatically send a signal of a door opened condition so that patient consumption information is recognized by a monitoring center (col 8, Ins 59-67).

For claim 3, Depeusinge discloses transmitting a status of a door to a remote receiver (col 4, lns 8-10), but does not disclose transmitting a unique identifier along with the status of a door. De La Huerga discloses transmitting a unique identifier to a remote receiver (col 57, lns 59-67; col 58, lns 1-10; Fig. 47). It would have been obvious to transmit both a door status and unique identifier in order to conserve transmission power by transmitting two types of data via one signal.

For claim 4, Depeusinge discloses a clock apparatus in at least indirect signal communication with said transmitter for generating a timestamp (col 4, lns 1-10; Fig. 1, items 11 and 18) and transmitting a status of a door to a remote receiver (col 4, lns 8-10), but does not disclose transmitting a date and timestamp along with the status of a door. De La Huerga, however, discloses generating a date and timestamp (col 8, lns 20-35). It would have been obvious to transmit not only a door status, but also a date and timestamp in order to conserve transmission power by transmitting two types of data via one signal.

For claim 7, Depeusinge discloses transmitting a status of a door to a remote receiver (col 4, lns 8-10), but does not disclose transmitting a unique identifier of a door along with the status of a door. De La Huerga discloses transmitting a unique identifier of a porthole to a receiver (col 31, lns 16-32; Fig. 30, items 20, 820). Even though De La Huerga discloses a porthole unique identifier and not a door unique identifier, it is obvious that either identifier identifies particular data relating to medication within the vial/volume. In addition, it would have been obvious to transmit both a door status and

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unique identifier of a door/porthole in order to conserve transmission power by transmitting two types of data via one signal.

For claim 8, Depeusinge discloses a transmitter but does not disclose that the transmitter is a two-way pager telemetry system (Fig. 1, item 18). De La Huerga discloses a transmitter that functions as a two-way pager telemetry system (col 12, Ins 7-11 and 34-43; col 48, Ins 41-50). It would have been obvious to include a bidirectional pager so that questions and answer are communicated between a remote monitoring system and a patient.

For claim 9, Depeusinge discloses a remote receiver, but does not disclose a database connected through a network. De La Huerga, on the other hand, discloses a remote receiver connected to a database through a network, such that when said receiver receives a signal from the transmitter, the receiver converts said signal to an electronic mail and transmits said electronic mail to said database through said network (col 8, Ins 59-67; col 9, Ins 1-11; col 12, Ins 44-48; col 22, Ins 28-35; col 48, Ins 41-50; col 60, Ins 55-60). It would have been obvious to include transmitting electronic mail to a network database so that physicians are aware of patients in need of prescriptions and may write prescriptions in a timely manner.

For claim 14, Depeusinge does not disclose a data entry device, however, De La Huerga discloses a data entry device in at least indirect signal communication with said transmitter such that data entered into said remotely monitored medication delivery system is transmitted to said remote receiver by said transmitter (col 11, Ins 61-65; col

12, Ins 44-56; col 19, Ins 17-43). It would have been obvious to include a data entry device so that data is retained in memory for future use.

For claims 16 and 17, Depeusinge does not disclose data that includes a predetermined code indicative of a patient's condition or specific patient symptom. However, De La Huerga discloses monitoring a patient's condition and specific patient symptom. Even though De La Huerga does not disclose a code indicative of a specific patient symptom or patient condition, it would have been obvious that both condition and symptom are converted to some sort of code in order to condense transmitted information.

For claim 25, Depeusinge does not disclose a blood pressure monitor for recording a patient's blood pressure. De La Huerga, on the other hand, discloses a blood pressure monitor for recording a patient's blood pressure in at least indirect signal communication with a transmitter such that the blood pressure is communicated to a remote receiver through the transmitter (col 5, Ins 60-67; col 6, Ins 1-6). Even though De La Huerga does not disclose that the blood pressure monitor is digital, it would have been obvious that a digital blood pressure monitor is most desirable to obtain accurate blood pressure readings. In addition, it would have been obvious to transmit patient blood pressure to a remote location so that a patient remains in one location while the patient's blood pressure is measured, thereby eliminating the chance of patient injury.

For claim 30, Depeusinge discloses the remote patient notification system comprises a communication system selected from the group consisting of telephone and a radio signal, but does not disclose a communication system selected from the

group of a pager, a cellular phone, and a telemetry RF frequency (col 3, Ins 56-58; col 4, Ins 28-31). De La Huerga discloses a communication system selected from the group of a pager, a cellular phone, and a telemetry RF frequency (col 12, Ins 7-11 and 34-38). It would have been obvious to communicate via pager so that information relating to prescription instructions are easily communicated between medical staff and patients.

8. Claims 5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518), and further in view of Shusterman (US 6,304,797).

For claim 5, Depeusinge discloses transmitting a status of a door to a remote receiver (col 4, Ins 8-10), but does not disclose a GPS in indirect communication with said transmitter. Shusterman discloses a GPS in indirect communication with a transmitter wherein position is generated and transmitted to a remote site (col 3, Ins 37-60; col 10, Ins 10-29; Fig. 5, item 510). It would have been obvious to transmit both a door status and position data from a GPS in order to conserve transmission power by transmitting two types of data via one signal.

For claim 12, Depeusinge does not disclose a digital thermometer in at least indirect signal communication with said transmitter for recording patient temperature. Shusterman, however, discloses a digital thermometer in at least indirect signal communication with said transmitter for recording a patient's temperature, wherein said temperature can be communicated to the remote receiver through the transmitter (Fig. 1, item 218; Fig. 5, items 218, 506; col 3, Ins 55-67; col 10, Ins 27). Even though Shusterman does not specifically disclose a digital thermometer, it would have been

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obvious that a digital thermometer is most desirable to obtain accurate temperature readings. Furthermore, it would have been obvious to measure a patient's body temperature and send the temperature data to a remote receiver so that medical staff prescribes the most appropriate medicine to a patient.

For claim 13, Depeusinge discloses a memory device for storing data, but does not disclose storing temperature data prior to transmission (col 3, lns 38-40; Fig. 1, item 1). Shusterman, however, discloses a memory device for at least temporarily storing temperature prior to transmission (col 4, lns 24-26 and 41-44; col 5, lns 17-34). It would have been obvious to store temperature data prior to transmission so that temperature data is compared to threshold values to determine if a temperature exceeds a predetermined range, thus, sending an alarm signal.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518), and further in view of Rasmussen (US 2004/0012502).

Depeusinge does not disclose a data encryption device; however, Rasmussen discloses a data encryption device in at least indirect signal communication with a transmitter, wherein any transmission is received and encrypted by said data encryption device prior to transmission by said transmitter (paragraph 0040). It would have been obvious to include a data encryption device to encrypt data prior to transmitting data to secure the data by preventing the signal from being intercepted and interpreted.

10. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518) and De La Huerga (US 6,529,446), and further in view of Curkendall et al. (US 6,995,675).

For claim 10, Depeusinge does not disclose encrypting electronic mail; however, Curkendall discloses the feature of an encryption system where electronic mail is encrypted prior to transmission (col 31, Ins 30-38 and 55-61). It would have been obvious to include a data encryption device to encrypt electronic mail prior to transmitting in order to secure the data by preventing the signal from being intercepted and interpreted.

For claim 11, Depeusinge does not disclose a secure database; however, Curkendall discloses the feature of a secure database (col 31, Ins 30-38 and 55-61). It would have been obvious to include a secure database so that information received by the database remains secure.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518), and further in view of Weinberger (US 5,408,443).

Depeusinge does not disclose an alphanumeric keypad as a data entry device; however, Weinberger discloses an alphanumeric keypad as a data entry device (Fig 4, item 25; col 6, Ins 59-65; col 11, Ins 46-55; Fig. 2, item 42). It would have been obvious to include an alphanumeric keypad so that a patient or medical staff inputs pertinent instructions into the system regarding a particular prescription.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Depeusinge (US 6,625,518), and further in view of Conway (US 6,822,571).

Depeusinge discloses transmitting patient data to a remote receiver through a transmitter, but Depeusinge does not disclose a digital scale for recording a patient's weight. Conway discloses a scale in indirect signal communication with a transmitter for

measuring a patient's weight and transmitting the weight to a remote receiver through a transmitter (col 4, lns 54-65; Fig. 4, item 10, 38, 45). Even though Conway does not disclose that the scale is digital, it would have been obvious that a digital scale is most desirable to obtain accurate weight readings. In addition, it would have been obvious to transmit patient weight to a remote location so that a patient remains in one location while the patient's weight is measured, thereby eliminating the chance of patient injury.

Allowable Subject Matter

13. Claims 32-37 and 40 are allowed. The following is a statement of reasons for the indication of allowable subject matter: A remotely monitored medication delivery system comprising: a plurality of dosage containment units, each unit defining an internal volume and having at least one moveable at plurality of dosage containment units, each unit defining an internal volume and having at least one moveable door defining an opening thereto, wherein said plurality of units are arranged in a sequential order such that each of the plurality of doors except a first door and a last door has one preceding door and one succeeding door, a mechanical interlock system engaged with said plurality of doors such that the interlock system locks each succeeding door until the door immediately preceding said succeeding door is opened; a sensor in signal communication with the at least one moveable door for monitoring the status of said door and producing a signal indicative of said status, wherein each of said plurality of doors includes a unique electronic door identifier such that the unique electronic door identifier is transmitted to the transmitter along with the signal; a transmitter in signal

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communication with said sensor for receiving the signal from said sensor and transmitting the signal to a remote receiver, wherein said transmitter is activated to send the signal automatically when said sensor senses that one of the plurality of doors has been opened; an electronic system identifier uniquely indicative of the particular remotely monitored medical system, wherein said electronic system identifier is transmitted to the remote receiver along with the signal; a clock apparatus in at least indirect signal communication with said sensor and said transmitter, wherein the date and time is generated by the clock and transmitted to the transmitter for transmission to the remote receiver when the sensor indicates that one of the plurality of doors has been opened; a data entry device in at least indirect signal communication with said transmitter such that data entered into said remotely monitored medication delivery system is transmitted to said remote receiver by said transmitter; and an encryption device in at least indirect signal communication with said transmitter, wherein any transmission is received and encrypted by said data encryption device prior to transmission by said transmitter.

14. Claims 38 and 41 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

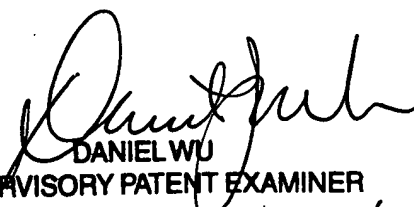
Siegel (US 6,594,549), Matsushita et al. (US 2002/0093429), Carrender et al. (2004/0008123), and Breimesser et al. (US 6,626,358) disclose drug monitoring systems.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Mehmood whose telephone number is (571) 272.2976. The examiner can normally be reached on M-F from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Daniel Wu, can be reached at (571) 272.2964. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer A. Mehmood
November 28, 2006


DANIEL WU
SUPERVISORY PATENT EXAMINER
12/10/06